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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/682,517	09/13/2001	Heidi Sue Dodson	020503-01-CA	2611

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EXAMINER

GUO, LYND A T

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 09/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/682,517

Applicant(s)

DODSON ET AL.

Examiner

Lynda T Guo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 1-10 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/13/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

CASE COPY

DETAILED ACTION***Status of the Application***

The IDS PTO1449 (Paper No. 4) received on 05/22/02 has been entered.

Claims 1-10 are considered here.

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of legal phraseology and a grammatical error was found (i.e. the fragment "radiolabeled first substrate, and a radiolabeled second substrate in the presence of absence of a test compound" should be omitted/corrected. Correction is required. See MPEP § 608.01(b). A new abstract on a separate page is requested.

Drawings

3. The drawings are objected to because of insufficient labeling of Figure 3. The plate in the figure does not disclose the contents of each well nor does it disclose any numerical data, thus interpretation of results is not possible. A proposed drawing correction or corrected

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drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-10 are directed to a method for identifying an inhibitor of a dual substrate enzyme.

Example 1 on page 10 of the present specification shows a method for the identification of inhibitors. Results of Example 1 are depicted in Figure 3.

This is not enabling for the claimed invention because results shown for a single assay are meaningless where one does not know their accuracy. No inhibitors of any enzymes are taught in the specification as originally filed.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claim 1 recites the limitations "the radiolabeled portion", "the non-radiolabeled first substrate", "test compound" and "the enzyme-radiolabeled first substrate" in lines 3, 7, 9 and 11, respectively. There is insufficient antecedent basis for these limitations in the claims.

8. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The omitted steps are: the correlation step(s) that discloses how comparing scintillation counts, as recited at the end of the claim, leads to the identification of an inhibitor as recited in the preamble said claim. Standard method steps include contacting, determining and correlating.

9. Claim 4 recites the limitation "the enzyme" in line 1. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (i.e. the claim fails to particularly point out whether the recited resin refers to the "capture resin" or the "scintillant resin" in Claim 1).

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11. Claims 2, 3-4 and 6 are rejected to because of the following: said claims are improper Markush type claims. Appropriate correction is required.

Examiner suggests the following:

For claims 2 and 6, amend the claims to read, "...selected from a **group consisting of...**"

For claims 3 and 4, amend the claims by omitting the words, "selected from".

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

13. Claims 1-4 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Reynolds, et al (Patent No. US 20010031477 A1).

Reynolds discloses of scintillation proximity assays useful for measuring the activity of fatty acid biosynthesis enzymes as well as for assessing a compound's ability to modulate the activity of a fatty acid biosynthetic enzyme (see page 1, abstract; pages 2-3, paragraphs 11-12, 14-17; page 4, paragraphs 43; page 5, paragraph 49 and 54; page 8, claims 1 and 7). Reynolds' method includes the use of a fatty acid biosynthesis enzyme that requires dual substrates, one of which is

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an acyl carrier protein, and the method of detection involves the use of scintillation proximity assay resin on a radiolabeled product that was enzymatically modified by said enzyme.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds (Patent No. US 20010031477 A1) in view of Mathews (Mathews, C.K., and van Holde, K.E., *Biochemistry*-Second Edition, 1995).

The claims differ from Reynolds teachings in that claims 5 and 6 specify particular classes of enzymes. Although Reynolds, above, does not specifically disclose phosphate transfer enzymes in his invention, Reynolds does disclose that the assays can be readily adapted to the analysis of OTHER enzymes involved in the fatty acid biosynthetic pathway (page 5, paragraph 49). Mathews teaches that fatty acid synthesis is controlled in part by phosphorylation and dephosphorylation, i.e. via kinases and phosphatases, (page 654), thus qualifying the enzymes in claims 5 and 6 as enzymes involved in the fatty acid biosynthetic pathway. Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the assays as disclosed by Reynolds for use with phosphate transfer enzymes.

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16. Claims 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds (Patent No. US 20010031477 A1) in view of Gul, et al (Gul, S., Sreedharan, S.K., and Brocklehurst, K., Enzyme Assays – Essential Data, 1998).

Claim 7 is directed to an ionically charged resin; Claims 9 and 10 include a filtration step for the removal of unreacted radiolabeled substrate. Reynolds' invention does not include a separation step for the product and residual substrate. However, Reynolds recites that, "the use of SPA [Scintillation Proximity Assay] obviates the need for separation of a radioactive product from the radiolabeled substrate and milieu in which it is produced" (page 4, paragraph 40). Gul, et al, teaches that, "The success of a radiometric assay relies on the efficient separation of the product formed during the reaction from residual substrate (either of which may be radiolabeled) and its sensitivity is dependent upon the specific radioactivity of the compound" (page 37). Gul, et al, further teaches that there are various techniques used to separate product formed from residual substrate, including adsorption of product by insoluble adsorbent and filtration (pages 38-39). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Reynolds' invention by including a separation step so as to increase the sensitivity of the assay.

Claim Objections

17. Claim 1 is objected to because of the following informalities: (1) the claim does not appear to be numbered; (2) the intention for the inclusion of the sentence fragment, "radiolabeled first substrate, and a radiolabeled second substrate, in the presence or absence of a test

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compound" in lines 8-9 is unclear. Appropriate correction is required. For the purpose of this examination, Examiner will assume that this fragment is a typo and will examine the claim to read without this fragment.


18. Claims 2-10 are objected to because of the following informalities: Dependent claims should begin with a definite article (i.e. The claims should read --The method according to claim--.) Appropriate correction is required.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda T Guo whose telephone number is (703) 605-1200. The examiner can normally be reached on Mon - Fri (8:00am - 4:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K McKane can be reached on (703) 308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Lynda T Guo
Patent Examiner
September 13, 2002


RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200